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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,955	04/25/2000	Yvonne E. Penfold	PM 266810	8900

909 7590 01/04/2002

PILLSBURY WINTHROP LLP  
1600 TYSONS BOULEVARD  
MCLEAN, VA 22102

EXAMINER
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FIELDS, IESHA P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/557,955

Applicant(s)

PENFOLD ET AL.

Examiner

Iesha P Fields

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicant's amendment filed September 24, 2001 (Paper No. 6) has been received and entered. Claims 9-10 were amended consequently claims 2-11 are pending in the instant application.

#### ***Response to Amendment***

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

#### ***Claim Rejections - 35 USC § 102***

1. Claims 9-10 rejected under 35 U.S.C. 102(e) as being anticipated by May et al. is withdrawn in view of Applicants amendment to the claims.

#### ***Claim Rejections - 35 USC § 103***

2. Claims 2-8 and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over May et al. in view of Sawai et al. is withdrawn in view of Applicants amendment to the claims.

***New Grounds for Rejection***

***Claim Rejections - 35 USC § 103***

3. Claims 2-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Sawai et al. and May et al further in view of Harlow and Lane.

The claims are drawn to an assay device and a reagent wherein the device comprises an immobilized anti-rabbit antibody and the reagent is a coloured latex particle sensitized to a murine monoclonal antibody and a rabbit antibody.

Sawai et al. (US Patent 4,224,304) teach of a method of preparing insoluble carrier particles such as coloured latex particles. Sawai et al. further teach of a method of preparing antibody sensitized latex particles. Sawai et al. further teach that the latex particles ideally have a diameter of 0.3 to 0.6 microns.

May et al. (US Patent 5,622,871) disclose an assay device wherein a particulate direct label is sensitized with a specific binding agent and a non-specific protein to form a complex which can be detected.

Harlow and Lane (Antibodies; A Laboratory Manual pp 608-632) teach of sensitizing a protein of interest with a non-specific protein in order to block non specific binding.

Given that 1) May et al. has taught of an assay device wherein a particulate direct label is sensitized with a specific binding agent and a non-specific protein to form a complex which can be easily detected and that 2) Sawai et al. has taught of a method of preparing coloured latex particles sensitized to antibodies and that 3) Harlow and

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Lane teach of sensitizing a protein of interest with a non-specific protein in order to block non specific binding it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a reagent and/or an assay device comprising a particulate sensitized to a binding agent such as an antibody. One would have been motivated to make such a reagent or device because they have wide industry application and can be used as diagnostic tools.

The Applicants arguments regarding the fundamental feature of the invention (i.e. a co-sensitized label reagent) has been noted. However, this aspect of the invention is well know in the art (See Harlow and Lane reference above). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify a standard binding techniques such as that taught by Harlow and Lane and expect a reasonable amount of success.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ilesha Fields

December 31, 2001



MARK NAVARRO  
PRIMARY EXAMINER